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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/622,719

10/18/2000

Hubert Loewenheim

24356

1261

26389

7590

03/15/2005

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EXAMINER

VIVLEMORE, TRACY ANN

ART UNIT

PAPER NUMBER

1635

DATE MAILED: 03/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 09/622,719	<b>Applicant(s)</b> LOEWENHEIM, HUBERT	
	<b>Examiner</b> Tracy Vivlemore	<b>Art Unit</b> 1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 28, 31 and 63 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28, 31 and 63 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

#### ***Claim Rejections - 35 USC § 112***

Claims 28, 31 and 63 are maintained as rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. This is a written description rejection.

Claims 28, 31 and 63 are drawn to methods that require antisense molecules targeted to any mammalian p27<sup>kip1</sup>. The specification does not disclose the structure (i.e. nucleotide sequence) of any antisense molecules targeted to mammalian p27<sup>kip1</sup>, nor does it disclose the target sequence for any mammalian p27<sup>kip1</sup> or the common structural elements (e.g. regions of homology) for mammalian p27<sup>kip1</sup>. The prior art at the time of the invention provided two antisense molecules targeted to one species of mammalian p27<sup>kip1</sup> (human p27<sup>kip1</sup>) and disclosed the nucleotide sequence encoding three species of mammalian p27<sup>kip1</sup>.

Claims 28, 31 and 63 encompass methods that inhibit any mammalian p27<sup>kip1</sup> mRNA, including the homologs of p27<sup>kip1</sup> from mammalian organisms which were neither described in the specification nor known in the prior art at the time of invention. The genus of mammalian p27<sup>kip1</sup> is broad, encompassing any mammalian organism and the species encompassed within the genus are highly variant (for example, with regard

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to nucleotide sequence). At the time of invention, p27<sup>kip1</sup> from three mammals was known in the prior art, however knowledge of three homologs of p27<sup>kip1</sup> is not sufficient to describe all homologs of p27<sup>kip1</sup> from all mammals. The specification does not correct the deficiencies of the prior art, describing no homologs of p27<sup>kip1</sup> from any other mammal.

In addition to the broad genus of mammalian p27<sup>kip1</sup> that are the targets of the claimed methods the antisense sequences that would be used to perform the claimed methods do not meet the written description provision of 35 USC 112, first paragraph. Since the genus of the targeted mammalian p27<sup>kip1</sup> has not been described, the genus of antisense sequences that would target and inhibit these undescribed species is also not described in the prior art. The two antisense molecules known in the art at the time of invention are not sufficient to adequately describe the genus of antisense sequences that would be required to practice the full scope of the claimed methods. The specification does not correct this deficiency, because none of the species encompassed by the genus are described in the specification.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

With the exception of the antisense sequences described in the prior art, the skilled artisan cannot envision the detailed chemical structure of the encompassed

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polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd, 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF'S were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir.1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics', in other words; it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the example does, does not necessarily describe the cDNA itself. No sequence information indicating which nucleotides constitute human cDNA appears in the patent, as appears for rat cDNA in Example 5 of the patent. Accordingly, the specification does not provide a written description of the invention of claim 5.

Therefore, only the two antisense sequences disclosed in the prior art (Hauser et al. (Cell Growth and Differentiation, Vol. 8, Feb 1997, p 203-211) of record), but not the full breadth of the claim, meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed in the prior art are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

### ***Response to Arguments***

Applicant's arguments filed 12/27/2004 have been fully considered but they are not persuasive. In response to the rejection of record under 35 USC 112, first paragraph for lack of adequate written description, Applicant argues that the amended claims are adequately described. Applicant argues that the Examiner has not provided a basis for stating the genus of p27<sup>kip1</sup> is variant with regard to nucleotide sequences and refers to previous arguments demonstrating 85% homology between the three known mammalian p27<sup>kip1</sup>. This is not persuasive as this demonstrates that the known mammalian p27<sup>kip1</sup> have variability of 15%. Further, as stated in the rejection, the disclosure of p27<sup>kip1</sup> from three species does not describe p27<sup>kip1</sup> from the thousands of mammalian species estimated to exist today. The known sequences are not sufficient to describe the full scope of p27<sup>kip1</sup> targeted by the claimed method, which is directed to any mammal, including those that are unknown as of the present time. Without adequate description of what is being targeted, antisense sequences to these targets cannot be described.

Applicant has submitted a declaration by Jonathan Kil describing experiments using 14 antisense sequences directed to the mouse homolog to p27<sup>kip1</sup> that reduced expression of p27<sup>kip1</sup> in mouse cells and asserts that this provides evidence for adequate written description of the instant specification. This is not persuasive as the question of whether antisense to p27<sup>kip1</sup> will decrease expression of p27<sup>kip1</sup> is not at issue.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Tracy Vivlemore  
Examiner  
Art Unit 1635

TV  
March 7, 2005

SEAN MCGARRY  
PRIMARY EXAMINER  
1635